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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,387

01/05/2006

David Peter Shaw

PL10-002

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WELLS ST. JOHN P.S.
601 W. FIRST AVENUE, SUITE 1300
SPOKANE, WA 99201

EXAMINER

SCHILLINGER, ANN M

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

09/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,387	Applicant(s) SHAW, DAVID PETER	
	Examiner ANN SCHILLINGER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-12 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-12 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/22/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15, 16, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The above claims describe intermeshing loops that have not been described by the Applicant's specification and drawings.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is comparing the knitted wire to woven wire which does not further limit the physical attributes of the claimed invention. In addition, there is no antecedent basis for the woven wire. Further, there are limitations describing the material comprising the woven wire which would be essential to determine its flexibility.

Claims 10-12, 14, and 18 are rejected under 35 U.S.C. 112, second paragraph. Claim 10 recites the limitation "the or each flap" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9-11, and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini (EP 0 331 345 A2) in view of Gabbay (US Pat. No. 6,869,444). Silvestrini discloses the following of the claimed invention: a prosthetic valve in the form of a flap valve which includes at least one flap (12) arranged to allow movement of liquid through the valve only in one direction, the or each flap being made of a flexible openwork structure of a medically acceptable metal (col. 3, lines 2-23). A single flap (12) arranged to close against a supporting wall (16) mounted upon a peripheral stent (14). Silvestrini discloses the limitations of claims 3 and 5 as shown in Figure 1. Silvestrini discloses the peripheral rib of claim 6 in col. 2, lines 23-26. Silvestrini discloses the peripheral stent of claim 7 in element 14. Silvestrini discloses the following of claims 10 and 11: a method of promoting tissue growth and endothelialisation, minimizing the risk of foreign body infection following the fitting of a prosthetic valve in a living subject (col. 1, line 4-6), said method including the provision of a prosthetic valve in which the or each flap (12) is made of a flexible open work structure of a medically acceptable metal (col. 3, lines 2-23), wherein the flexible openwork structure is selected from the group consisting of: knitted wire comprising intermeshing loops and chainmail (please see Figures 2, 3; col. 2, lines 27-38, and col. 3, lines 19-31).

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However, Silvestrini does not disclose the prosthetic's flexible openwork structure being made from knitted wire. Gabbay teaches a cardiac prosthesis constructed from a titanium alloy knitted wire in col. 10, line 63 through col. 11, line 10 and col. 11, line 57 through col. 12, line 5 for the purpose of providing the prosthesis with the desired resiliency. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use knitted wires to construct the prosthesis in order to provide the prosthesis with the desired resiliency.

Please note that the examiner is interpreting the term "knit" according to its dictionary definition: "to form a fabric by interlacing yarn or thread; to weave by making knots or loops" (knit. Dictionary.com. Webster's Revised Unabridged Dictionary. MICRA, Inc. <http://dictionary.reference.com/browse/knit> (accessed: April 17, 2008)).

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini in view of Gabbay, further in view of Yang (US Pub. No. 2002/0138138). Silvestrini, as modified by Gabbay, discloses the invention substantially as claimed, however, they do not disclose placing an inert degradable coat over the valve. Yang teaches this coating in paragraph 0059 for the purpose of reducing the wear of the prosthetic parts. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use this coating in order to reduce the wear of the prosthetic parts.

Response to Arguments

Applicant's arguments filed 7/22/2008 have been fully considered but they are not persuasive. The Applicant contends that current interpretation of the term "knit" is inappropriate due to the descriptions of woven and knitted wires provided in the specification. While claims in

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a pending application are to be given their broadest, reasonable interpretation in light of the specification, limitations from the specification should not be read into the claims. The Applicant has described the use of woven and knit wires of in the specification; however, the Applicant may only claim the benefit of these descriptions into the claims if the specification explicitly states that these descriptions are the only definitions to be applied to the terms. The applicant may act as his or her own lexicographer to specifically define a term the written description must clearly redefine the claim term and set forth the definition so as to put one reasonably skilled in the art on notice of how the applicant intended to define that claim term. Therefore, the current interpretation of the term knit has been maintained.

Regarding claim 12, it is well-known in the art that PTFE is an inert material and may be formulated to be degradable; therefore it would have been obvious one of ordinary skill in the art at the time invention was made to use a PTFE coating to protect the prosthesis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./

Examiner, Art Unit 3774

/William H. Matthews/

Primary Examiner, Art Unit 3774